

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-8, in the reply filed on April 3, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 9-11 are withdrawn, as drawn to a non-elected invention.

### ***Claim Objections***

Claim 5 is objected to for the absence of a space between "claim" and "1".

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of "or an ortholog thereof" with regard to SEQ ID NO: 2. The specification at page 11 defines orthologs of HIO103.1 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO103.1 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not

Art Unit: 1638

limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, the list of possible functional activities is open ended, and most of the activities listed are generic, such as catalytic activity, binding activity, and signaling activity, wherein these functional activities are found in many divergent polypeptides that are not associated with producing a high oil phenotype in a plant. The specification also discloses that the term “orthologs” infers evolutionary relatedness of sequences. However, determination of evolutionary relatedness of sequences is subjective. In addition, the specification does not set forth any protein motifs or 3-dimensional structure that would identify a sequence as an ortholog of HIO103.1. Thus, the use of “ortholog” in the claim does not set forth the metes and bounds of the claimed invention.

5. Claims 1 and 6, and claims 2-5, 7 and 8 dependent thereon, are indefinite in the recitation of “high oil phenotype relative to control plants” and “altered oil content phenotype relative to control plants”, given that it is unclear what is encompassed by “control plant” and the specification fails to set forth the metes and bounds of this term.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

Art Unit: 1638

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to transgenic plants comprising a plant transformation vector comprising a sequence that encodes HIO103.1 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an ortholog thereof, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant. However, the specification only provides a plant transformed with a nucleic acid encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that when overexpressed produces a high oil phenotype in the plant. The specification does not identify any other sequences that produce a high oil phenotype, including any sequences that could be considered orthologs of HIO103.1.

8. The specification at page 11 defines orthologs of HIO103.1 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO103.1 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, the specification does not describe any structural features of the polypeptides that confer any of the recited functional activities or that are required to confer the claimed function of producing a high oil phenotype in a transformed plant. Applicants are claiming a genus of sequences. However, only one sequence has been provided.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a

Art Unit: 1638

written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention". See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

***Claim Rejections - 35 USC § 112***

9. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plants comprising a plant transformation vector comprising a sequence that encodes the HIO103.1 polypeptide comprising the amino acid sequence of SEQ ID NO: 2, wherein the transgenic plant has a high oil phenotype, does not reasonably provide enablement for a transgenic plant comprising a plant transformation vector comprising a sequence that encodes the HIO103.1 polypeptide that is an ortholog of the amino acid sequence of SEQ ID NO: 2, and wherein the transgenic plant has a high oil phenotype. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are drawn to transgenic plants comprising a plant transformation vector comprising a sequence that encodes HIO103.1 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an ortholog thereof, and wherein the plant has a high oil phenotype relative to control plants and methods of producing said transformed plant.

Art Unit: 1638

10. The specification at page 11 defines orthologs of HIO103.1 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structure. And at page 8, the specification states that an ortholog of HIO103.1 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Bork (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least).

However, the specification does not set forth how expression of the HIO103.1 polypeptide confers a high oil phenotype on a transformed plant. The specification states that the functional activity of HIO103.1 and orthologs thereof may be any of a signaling activity, a binding activity, a catalytic activity or a cellular or extra-cellular localizing activity. Yet none of these functional activities are demonstrated for SEQ ID NO: 2 or for any orthologs thereof, and the specification does not teach how to assay for any of these functional activities.

Thus, given the unpredictability of identifying sequences that exhibit the same functional activity and producing a high oil phenotype in a transgenic plant; the lack of guidance in the specification for the structural and functional characteristics of sequences that are orthologs of SEQ ID NO: 2 and will produce a high oil phenotype in a plant; and given the lack of working examples of any sequences other than SEQ ID NO: 2 that will produce a high oil phenotype in a plant; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638